

## SUMMARY OF CLAIMS

Claims 1, 2, 5-12, 14-26 and 37-53 are pending. Reconsideration is respectfully requested in light of the following remarks.

Claims 27-36 are withdrawn.

Claims 3,4 and 13 are canceled.

Claims 1, 2, 5-12, 14-26, and 37 are currently amended.

Claims 38-53 are new.

No new matter is entered by the amendments.

Support for the amended and new claims can be found, for example, as listed below:

<b>Amended/New Claim #</b>	<b>Support</b>
1	Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
2	Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
5 to 10	Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
11 and 12	Figs. 2A+B; Fig. 11; Fig. 14 specification page 22, lines 5-14; page 8, lines 23-32 page 9, line 4 and page 27, lines 8-19
14 and 15	Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
16 to 26	Figs. 2A+B; Fig. 11; Fig. 14 specification page 22, lines 5-14; page 8, lines 23-32 and page 9, line 4; page 27, lines 8-19
37	Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
38	Original claim 1; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
39	Original claim 1; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 7, lines 20-29
40	Original claim 1; Figs. 2A+B; Fig. 7; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 16, lines 10-13
41	Original claim 1; Figs. 2A+B; Fig. 3; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 8, line 33 to page 9, line 17
42	Original claim 8; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4

Amended/New Claim #	Support
43	Original claim 8; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 7, lines 20-29
44	Original claim 8; Figs. 2A+B; Fig. 7; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 16, lines 10-13
45	Original claim 8; Figs. 2A+B; Fig. 3; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 8, line 33 to page 9, line 17
46	Original claim 11; Figs. 2A+B; Fig. 11; Fig. 14 specification page 22, lines 5-14; page 8, lines 23-32; page 9, line 4 and page 27, lines 8-19
47	Original claim 11; Figs. 2A+B; Fig. 11; Fig. 14 specification page 22, lines 5-14; page 8, lines 23-32; page 9, line 4; page 27, lines 8-19 and page 7, lines 20-29
48	Original claim 11; Figs. 2A+B; Fig. 7; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 16, lines 10-13
49	Original claim 11; Figs. 2A+B; Fig. 3; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 8, line 33 to page 9, line 17
50	Original claim 37; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32 and page 9 line 4
51	Original claim 37; Figs. 2A+B; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 7, lines 20-29
52	Original claim 37; Figs. 2A+B; Fig. 7; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 16, lines 10-13
53	Original claim 37; Figs. 2A+B; Fig. 3; Fig. 11; specification page 22, lines 5-14; page 8, lines 23-32; page 9 line 4 and page 8, line 33 to page 9, line 17

## REMARKS

### Interview

Applicants wish to thank Examiner Kim for the courtesies extended to Applicants and Applicant's counsel in the interview on October 10, 2007, during which proposed claim amendments to overcome the outstanding rejections were discussed.

### Claim Rejections – 35 USC § 103

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner has rejected claims 1-26, and 37 under 35 U.S.C. 103(a) as being unpatentable over Lagally et al. (Sensors and Actuators B, 2000, vol. 63, pages 138-146; "Lagally" hereinafter) in view of Waller et al. (Applied Environmental Microbiology, 2000, vol. 66, no. 9, pages 4115-4118; "Waller" hereinafter).

Since claims 3, 4 and 13 are canceled the rejection with respect to these claims is moot.

The Examiner's rejection was based on the grounds that Lagally showed "a monolithic integrated microfluidic DNA amplification and capillary electrophoresis device, for explicit contemplated uses of, "manipulation, amplification, and CE separation of submicroliter volumes of DNA" (page 139, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph), wherein the device is disclosed as comprising: a) a PCR chamber (Figure 1(B) on page 140); and b) a capillary electrophoresis (CE) mechanism (Figure 1 page 140 and page 141, 2<sup>nd</sup> column, bottom paragraph)." The Examiner went on to state that while Lagally "explicitly contemplate[s] a microfluidic device for PCR and CE analysis, the artisans are not explicit in stating that their device is adapted for conducting immunocapture." Accordingly, the Examiner's grounds for rejection of claims 3-5, 9, 10, 13, 16-22 and 37 were further based on Waller who "disclose a method of immunocapture PCR assay for the purpose of detecting a pathogenic species, *Campylobacter jejuni* from food samples (see Abstract)." Applicants respectfully traverse the rejections.

Given the present form of claims 1, 2, 5-12, 14-26, 37 and newly presented claims 38-53, the references alone or in combination do not meet the criteria for a *prima facie* case of obviousness since the references alone or in combination do not teach or suggest each and every limitation of the claimed inventions.

Claim 1 recites a target detection system, the system comprising:

an immunocapture chamber integrated on a microfluidic device, the immunocapture chamber operable to capture a target provided to the immunocapture chamber through a microfluidic channel;

a DNA analysis chamber comprising a DNA analysis mechanism in fluid communication with the immunocapture chamber, the DNA analysis chamber integrated on the microfluidic device, the DNA analysis mechanism operable to perform DNA analysis on the target; and

at least one pneumatically actuated diaphragm pump integrated on the microfluidic device, each pump configured to pump a determined volume of fluid through the first microfluidic channel into the immunocapture chamber and pump a determined volume of fluid from the immunocapture chamber into the DNA analysis chamber.

As such, claim 1 recites in part a pneumatically actuated diaphragm pump integrated on the microfluidic device. Lagally instead teaches a manifold sealed to a chip for fluidic control on the chip. Waller is silent regarding fluidics control. Since neither Lagally or Waller teach or suggest a pneumatically actuated diaphragm pump integrated on a microfluidic device the references either alone or in combination fail to teach or suggest a limitation of the claimed inventions.

Additionally, the references do not provide motivation for inclusion of a pneumatically actuated diaphragm pump integrated on a microfluidic device. As mentioned Waller is silent regarding fluidics control. Lagally teaches fluidics wherein

“valves and vents were controlled by an aluminum manifold depicted in Fig. 2. Each manifold consists of an o-ring set into the base of the manifold that seals the manifold to the chip ... [and] Tygon tubing (1/8-in. OD) connects the manifold system via fluidics connectors (Upchurch, Oak Harbor, WA) to a set of computer-controlled solenoid valves that apply vacuum and pressure as required” (see page 139 second column last paragraph to page 140 first column first paragraph).

As such the device of Lagally does not include a pump integrated on a chip but instead employs a manifold coupled to a chip to provide fluidics control on the chip. Given the teachings of Lagally a person of ordinary skill in the art would not have been motivated to modify the device of Lagally to include a pneumatically actuated diaphragm pump integrated on the microfluidic device, each pump configured to pump a determined volume of fluid through the first microfluidic channel into the immunocapture chamber and pump a determined volume of fluid from the immunocapture chamber into the DNA analysis chamber as presently claimed.

Accordingly, the Lagally and Waller references alone or in combination do not teach, suggest or provide motivation for the claimed invention of claim 1. Since claims 2, 5-7, and 42-45 depend from claim 1 and therefore include every element of claim 1 including a pneumatically actuated diaphragm pump integrated on the microfluidic device, it follows that the references fail to teach, suggest or provide motivation for the claimed inventions.

Turning to claim 8, as presented the claim now recites at least one pneumatically actuated diaphragm pump integrated on the microfluidic device. As such, for the same reasons as discussed above the references do not teach, suggest or provide motivation for the claimed invention. Since claims 9, 10, 14, 15 and 42-45 depend from claim 8 and therefore include every element of claim 8 including a pneumatically actuated diaphragm pump integrated on the microfluidic device, it follows that the references fail to teach, suggest every element or provide motivation for the claimed inventions.

Claim 11 now recites a plurality of pneumatically actuated diaphragm pumps integrated on the microfluidic device. Again, for the same reasons as discussed above the references do not teach, suggest or provide motivation for the claimed invention. Since claims 11, 12, 16-26 and 45-49 depend from claim 11 and therefore include every element of claim 11 including a plurality of pneumatically actuated diaphragm pumps integrated on the microfluidic device, it follows that the references fail to teach, suggest every element or provide motivation for the claimed inventions.

Claim 37 now recites at least one pneumatically actuated diaphragm pump. As such, for the same reasons as discussed above the references do not teach, suggest or provide motivation for the claimed invention. Since claims 50-53 depend from claim 37 and therefore include every element of claim 37 including a pneumatically actuated diaphragm pump integrated on the monolithic device, it follows that the references fail to teach, suggest every element or provide motivation for the claimed inventions.

As absence of even a single criterion negates a *prima facie* case, a *prima facie* case of obviousness has not been met for claims 1, 2, 5-12, 14-26, 37-53. Accordingly, Applicants respectfully request that the present rejection be withdrawn.

### **Double Patenting**

Claims 1-26 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-39 of copending Application No. 10/750,533. Applicants traverse.

Since claims 3, 4 and 13 are canceled the rejection with respect to these claims is moot.

As to the remaining pending claims the rejection is acknowledged and will be addressed upon a finding of otherwise allowable subject matter.

### **Conclusion**

If prosecution of this application can be assisted by telephone, the Examiner is requested to call Applicant's undersigned attorney at (510) 663-1100.

If any fees are due in connection with the filing of this amendment (including any fees due for an extension of time), such fees may be charged to Deposit Account No. 500388 (Order No. UCALP031).

Dated: 12/3/07

Respectfully submitted,  
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